DEPARTMENT OF HEALTH AND SENIOR SERVICES

DIVISION OF LONG TERM CARE SYSTEMS

General Licensure Procedures and Enforcement of Licensure Regulations

Proposed New Rules: N.J.A.C. 8:43E-7

Authorized by: _____

Clifton R. Lacy, M.D., Commissioner, Department of Health and Senior Services

Authority: N.J.S.A. 26:2H-1 et seq. and N.J.S.A. 26:2H-5.10

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2003-297

Submit written comments by October 3, 2003 to:

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Long Term Care Systems

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The agency proposal follows:

Summary

On January 4, 2000, Governor Christine Todd Whitman signed into law legislative amendments to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., which require the Department of Health and Senior Services to adopt rules and regulations implementing a policy expected to reduce needle stick injuries to health care workers through mandatory usage of needles and other sharps containing integrated safety features or needleless devices. See P.L. 1999, c.311. In this manner, health care worker exposure to bloodborne pathogens is expected to be greatly reduced. Accordingly, sickness and injury rates and the administrative, social and personal costs associated with needle stick injuries are expected to drop. The legislation mandates that all health care facilities licensed by this Department be required to implement the use of safety sharps by January 4, 2001. In addition, the rules will apply to pre-filled syringes, as well. Although the enabling legislation provides for up to 36 months from the date of its enactment to require the use of safety devices for pre-filled syringes, there appears to be no rational policy reason to wait that long, since affordable and effective “add-on” devices are currently available for pre-filled syringes.

Since these rules will apply to all licensed health care facilities, without exception, they are proposed for inclusion in the Department’s general licensure procedure and enforcement chapter, N.J.A.C. 8:43E. Although the legislation

contains certain provisions permitting exceptions to the use of safety sharps in certain individual exceptions, there are no “wholesale” exceptions in the rule pertinent to any particular type of licensed health care facility. Accordingly, these rules are appropriately placed into the general licensure procedure chapter. As proposed, the new rules are as follows:

N.J.A.C. 8:43E-7.1 sets forth the requirement to use needles and sharp instruments containing integrated safety features or needleless devices. N.J.A.C. 8:43E-7.1(a) specifically requires all facilities to purchase for use by health care workers only available sharp devices containing integrated safety features or needleless devices designed to prevent needle stick injuries, in accordance with the statute. N.J.A.C. 8:43E-7.1(b) permits an exception to the general rule set forth in subsection (a), stating that facilities may utilize other appropriate sharp devices in instances where there is no “available” safety device containing integrated safety features, including devices with non-integrated, add-on safety features. N.J.A.C. 8:43E-7.1(c) mandates facilities to implement the requirements of these rules for both empty and pre-filled syringes upon the effective date of the rules. Although the enabling legislation specifies that the Department has up to 36 months to implement its requirements with regard to pre-filled syringes, add-on safety devices for pre-filled syringes are currently available on the open market at relatively low cost. Accordingly, there is no sound policy reason to wait the full 36-month period to implement the legislation regarding pre-filled syringes.

N.J.A.C. 8:43E-7.2 sets forth definitions applicable to the proposed new rules. Since many of the terms employed in the proposed rules have special meanings within the context of the new law, those terms are defined in this proposed section. Several of the terms, as noted herein below, are defined in the statute itself. Those statutorily defined terms are “department” and “needle stick injury.” The remainder of this proposed rule contains definitions for the terms “available," department," "emergency," “evaluation committee,” “facility,” "health care system," health care worker," "integrated safety features," "needleless device," and “sharp device(s).” The proposed definitions are necessary for the correct interpretation of the proposed new rules.

N.J.A.C. 8:43E-7.3 sets forth the requirement that all facilities or health care systems subject to these rules appoint a safety device evaluation committee. The proposed rule additionally sets forth the responsibilities of the evaluation committee, consistent with the statute. N.J.A.C. 8:43E-7.3(a) requires that every licensed health care facility or health care system appoint an evaluation committee to be responsible for evaluating and selecting sharp devices with integrated safety features or needleless devices for use by health care workers at the facility or within the system. N.J.A.C. 8:43E-7.3(b) requires that at least one half of the membership of the evaluation committee be comprised of health care workers whose duties include the use of sharp devices and, therefore, potential exposure to bloodborne pathogens and other potentially

infectious material. Where the evaluation committee is appointed by a health care system, every facility in the system must be represented on the evaluation committee through the appointment of a direct health care worker from each individual facility. N.J.A.C. 8:43E-7.3(c) requires every evaluation committee to establish and follow guidelines for determining which devices are to be purchased for use by facility staff. An example of such guidelines may be found in the June 1999 edition of the "California Guide to Preventing Sharps Injuries." As stated in the proposed rule, that guide is available by contacting the California Healthcare Association by phone, mail or via the internet. N.J.A.C. 8:43E-7.3(d) requires that all facilities develop and maintain policies and procedures for the continual review and evaluation of sharp devices as they are newly introduced and become available for purchase. Review of devices shall occur at a minimum frequency of once annually and policies and procedures are required to be reviewed and re-evaluated every three years.

N.J.A.C. 8:43E-7.4 governs waiver from the requirement to utilize available sharp devices with integrated safety features. N.J.A.C. 8:43E-7.4(a) requires each facility to develop policies and procedures for health care professionals to request waivers on a non-emergency basis. N.J.A.C. 8:43E-7.4(b) requires that non-emergency waivers be approved by the facility evaluation committee and may be approved only for a specific device to be used for a specific medical procedure to be performed on a specific patient class. In addition, in those cases where the evaluation committee determines that the use

of a safety sharp may potentially have a negative impact on patient safety or the success of a specific medical procedure, the evaluation committee is required to grant the waiver request. N.J.A.C. 8:43E-7.4(c) governs emergency use of non-safety sharps. The rule permits the use of non-safety sharps absent a waiver where two criteria are met. First, the health care professional using the device must determine that use of a safety sharp will potentially have a negative impact on patient safety or the success of a specific medical procedure. Second, within five days of the incident, the professional must make written notification to the facility evaluation committee, on forms prescribed by the Department, stating the reasons why it was necessary to use a non-safety sharp.

N.J.A.C. 8:43E-7.5 sets forth the reporting and recording requirements of the statute. 8:43E-7.5(a) requires that all facilities maintain a record of needle stick injuries in either a sharps injury log or an OSHA 300 Log. All log entries are required to include a description of the injury and the type and brand name of the sharp device involved in the injury. 8:43E-7.5(b) requires all facilities to report to the Department on a quarterly basis, all entries of needle stick injuries logged in accordance with the rule, as well as all waivers granted and the reasons therefor and all emergency uses by health care professionals of sharp devices not containing integrated safety features. 8:43E-7.5(c) requires facilities to generate a list of procedures for which there are no available safety devices and 8:43E-7.5(d) simply sets forth the address to which all reports shall be sent.

Social Impact

These proposed new rules require that all licensed health care facilities purchase needles and other sharp devices containing integrated safety features which help to prevent needle stick injuries to health care workers, thereby reducing their potential exposure to bloodborne pathogens which can cause severe injury, sickness and/or death. The legislation requiring the proposal and eventual adoption of these rules specifically finds and declares that "the use of conventional needles results in increased risk of HIV infection and hepatitis B and C to health care workers" and that "each year, from 150 to 200 health care workers die and many suffer chronic and debilitating diseases due to needle stick injuries." See N.J.S.A. 26:2H-5.10. In addition, the Legislature has declared that "concern with cutting health care costs has impeded the widespread use of advanced, safer technology" despite the fact that "equipment exists to prevent most injuries that result from needle stick injuries." Accordingly, in the interest of protecting health care workers from the spread of disease through unnecessary and accidental exposure to bloodborne pathogens, these rules are proposed to effectuate the aforementioned legislative mandate. For the aforesaid reasons, the proposed new rules are expected to have a positive social impact on health care workers.

While the proposed new rules are not expected to have a direct positive social impact on patients, no negative social impact is anticipated. The rules

provide for exceptions to the requirement of the use of safety sharps where they are contraindicated for specific procedures and specific patients and in emergency situations. Moreover, since the eventual adoption of these proposed new rules is expected to have a positive impact on the health care worker population, the requirement that all facilities impose a policy of protection against bloodborne pathogen exposure, even if it may increase costs, is likely to attract qualified health care personnel who might otherwise avoid a career due to the potential for danger.

These proposed new rules are also expected to have a positive social impact on the family and friends of health care workers as well as the remainder of the general public, since the use of safety sharps is anticipated to curb the spread of disease. Clearly, elimination or reduction of the risk to health care workers means reduction of the risk to their friends and families, as well, which benefits all members of the general public.

Economic Impact

As stated in the legislation requiring the proposal and eventual adoption of these proposed new rules, there exists concern that implementation of a policy requiring the use of safety sharps will negatively impact efforts to combat increasing health care costs. See N.J.S.A. 26:2H-5.10. Additionally, since needles and other sharp devices containing integrated safety features typically

are higher in cost than conventional needles and other sharps, health care facilities are likely to experience higher equipment costs in this area. However, it is not clear that such higher costs will necessarily result in higher overall costs to health care facilities. The use of safety devices is anticipated to have a positive impact on the health of facility staff by reducing the number of work-related injuries. This should have a positive impact on worker's compensation insurance premiums and reduce the significant costs associated with needle stick-related employee monitoring, absenteeism and follow-up care. Therefore, it is not unreasonable to expect some off-set of these costs through implementation of the requirements set forth in these proposed rules. Accordingly, the Department does not anticipate that there will be an overall significant economic impact to health care facilities.

Federal Standards Statement

Federal Occupational Safety and Health Act ("OSHA") laws and regulations applicable to licensed health care facilities impose standards governing the use of needles and other sharp devices containing integrated safety features in all licensed and unlicensed health care facilities. See P.L. 106-430; see also 29 C.F.R. §1910.1030. Federal Comprehensive Omnibus Budget Reconciliation Act (COBRA), Title XXII of the Public Health Active Labor Act (EMTALA), 42 U.S.C. §1395dd, and other provisions of the Federal Social Security Act governbing Medicare and Medicaid, are non-specific with respect to

the issues addressed in these proposed new rules. The standards contained in these proposed new rules are similar to those required by OSHA. However, these proposed new rules necessarily exceed the standards contained in the OSHA rules with respect to the requirement of facility evaluation committees, in accordance with the specific requirements set forth in State law; see N.J.S.A 26:2H-5.10 et seq. Although the Federal rules do not contain the evaluation committee requirement, the State law specifically contains that requirement. The policy for imposing the requirement of a facility evaluation committee is to maximize the success of the safe sharp device program, since the evaluation committees are responsible for evaluating devices on the market for purchase and reporting relevant information to the Department, among other things. The Department expects the requirement of an evaluation committee will result in no additional cost to licensed health care facilities, since it does not require facilities to hire additional staff. Furthermore, the requirement is not technology-dependent. Accordingly the requirement of an evaluation committee at the facility level is justified and warranted in order to adequately protect individuals from sharps injuries.

Jobs Impact

The proposed new rules are not anticipated to either increase or decrease the number of jobs available in health care facilities.

Agriculture Impact

This proposal will have no impact on the agricultural industry in New Jersey.

Regulatory Flexibility Analysis

Since N.J.A.C. 8:43E-1 governs general licensure procedure and licensure enforcement, it is applicable to all licensed health care facilities, including some which may employ under 100 people and, therefore, are defined as small businesses under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Although compliance with the rules in this chapter (see Summary above) may generate certain costs within small businesses (see Economic Impact above), those costs are not predictable because they will vary between facilities and are dependent upon the facts and circumstances of each case. The goal of these rules is to protect the general health, safety and welfare through prevention of needle stick injuries to all health care workers, regardless of the size of the facility in which they are employed. Accordingly, a flexible standard based upon facility size would fail to meet the intent of the rules and their enabling legislation. See N.J.S.A. 26:2H-5.10. Finally, the rules are straightforward and the Department foresees no need on the part of any facility to retain professional services in order to comply.

Smart Growth Impact Statement

The proposed new rules will have no impact on the achievement of smart growth or implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follows:

SUBCHAPTER 6. (RESERVED)

SUBCHAPTER 7. REQUIREMENT TO USE NEEDLES AND SHARP INSTRUMENTS CONTAINING INTEGRATED SAFETY FEATURES OR NEEDLELESS DEVICES

8:43E-7.1 Use of needles and sharp instruments containing integrated safety features

(a) All facilities shall purchase, for use by health care workers only available sharp devices containing integrated safety features or available needleless devices designed to prevent needle stick injuries, in accordance with N.J.S.A. 26:2H-5.10 through 5.16, as well as this subchapter.

(b) In cases where there is no available sharp device containing integrated safety features or needleless device, for a specific patient use, facilities shall utilize the appropriate sharp device that

is available for that specific patient use, including any sharp device which employs non-integrated, add-on safety features, until such time as an appropriate sharp device containing integrated safety features becomes available.

(c) The provisions of this section shall apply to both empty and pre-filled syringes upon the effective date of these rules.

8:43E-7.2 Definitions

(a) The following words and terms when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise:

"Available" means cleared or approved for marketing by the Federal Food and Drug Administration and commercially offered for distribution.

"Department" means the New Jersey Department of Health and Senior Services.

"Emergency" means an unforeseen circumstance involving a patient in need of immediate medical attention in

order to save the patient's life and/or limb or prevent serious and/or permanent injury.

“Evaluation committee” means a group of individuals appointed within each facility or health care system which satisfies the requirements of N.J.S.A. 26:2H-5.13 and N.J.A.C. 8:43E-7.3.

“Facility” means a health care facility licensed by the Department, pursuant to the provisions set forth in the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., as amended.

"Health care system" means a licensed health care provider/entity that either owns and operates more than one licensed facility within the State of New Jersey or can document operational control over more than one licensed facility within the State of New Jersey, but which is not a management company.

"Health care worker" or "health care professional" means a physician, physician assistant, advanced practice nurse, registered nurse, licensed practical nurse, or any other individual employed by the facility or having privileges at the

facility whose job duties require the use of sharp devices, as that term is defined herein.

"Integrated safety features" means needles and all other sharp instruments with engineered injury prevention protections in the form of a built-in safety feature or mechanism designed to protect the user of the sharp device from needle stick injuries.

"Needleless device" means a device that does not use needles for the following procedures:

1. The collection or withdrawal of bodily fluids after initial venous or arterial access is established;
2. Administration of medication or other fluids; or
3. Any other procedure involving potential for exposure to blood or other potentially exposed infectious material.

“Needle stick injury” means the actual or potential parenteral introduction, into the body of a health care worker, of blood or other potentially exposed infectious material, by any type of sharp device, as that term is defined in this section.

"Sharp device(s)" means needles and all other sharp instruments used by health care workers to administer patient care, the use of which creates the potential for exposure to blood or other potentially exposed infectious material, regardless of whether the specific patient being treated has been diagnosed with a bloodborne disease or infection.

8:43E-7.3 Requirement and responsibilities of evaluation committees

(a) Every licensed health care facility or health care system shall appoint an evaluation committee which shall be responsible for evaluating and selecting sharp devices with integrated safety features or needleless devices for use by health care workers at the facility or facilities.

(b) At least one half of all members of the evaluation committee shall be direct-care health care workers employed by the facility or health care system, whose job duties include the use of sharp devices to treat patients of the facility and resulting potential exposure to blood and other potentially exposed infectious material through accidental needle stick injuries. In the case of a health care system, not only shall at least one half of the evaluation committee be comprised of direct-care health care workers, but the evaluation committee shall

also include at least one direct-care health care worker from every facility within the health care system.

(c) In determining which needles and other sharp devices or needleless devices to purchase in compliance with these rules, every evaluation committee shall establish and follow guidelines for determining which devices are to be purchased for use by facility staff. An example of such guidelines may be found in the June 1999 edition of the "California Guide to Preventing Sharps Injuries." That manual is available by contacting the California Healthcare Association by telephone at (800) 494-2001 or (916) 928-5123, via the internet at **www.calhealth.org** or in writing at the following address:

California Healthcare Association
Publication Sales Center
1101 North Market Boulevard, #9
Sacramento, CA 95834

(d) All facilities shall develop and maintain policies and procedures for the continual review and evaluation of sharp devices or needleless devices as they are newly introduced and become available. Review of newly marketed devices shall occur at a minimum

frequency of once annually. The policies and procedures shall include a requirement that all health care workers receive appropriate training in the use of all safety devices, whether sharp or needleless, purchased for use during the course of their duties. Training shall be provided to the extent necessary to ensure the proper and appropriate use of all devices with integrated safety features or needleless devices used within the facility. The policies and procedures shall be reviewed and reevaluated every three years.

8:43E-7.4 Waiver from the requirement to utilize available sharp devices with integrated safety features or needleless devices

(a) All facilities shall develop policies and procedures setting forth a mechanism for health care professionals to request non-emergency waivers from the requirements set forth in N.J.A.C. 8:43E-7.1. All waiver requests shall be submitted to the evaluation committee on forms prescribed by the Department.

(b) Non-emergency waiver requests shall be presented to the evaluation committee for approval and shall be considered only for a specific device to be used for a specific medical procedure that shall be performed on a specific class of patients. In cases where

the evaluation committee determines that the use of a sharp device with integrated safety features may potentially have a negative impact on patient safety or the success of a specific medical procedure, the waiver request shall be granted by the evaluation committee.

(c) In the case of an emergency, a health care professional may utilize sharp devices which do not contain integrated safety features without a waiver, provided:

1. The professional determines that use of a sharp device with integrated safety features potentially may have a negative impact on patient safety or the success of a specific medical procedure; and

2. The professional making the determination required in (c)1 above, notifies the evaluation committee, in writing, on a form prescribed by the Department, within five days of the date the sharp device was used, of the reasons why it was necessary to use a sharp device without integrated safety features.

8:43E-7.5 Reporting and recording requirements

(a) All facilities shall maintain a record of needle stick injuries, either in a Sharps Injury Log or an OSHA 300 Log. All entries made pursuant to this subchapter shall include a description of the injury and the type and brand name of the sharp device involved in the injury.

(b) All facilities shall report to the Department on a quarterly basis, on forms prescribed by the Department, all entries of needle stick injuries logged in accordance with N.J.A.C. 8:43E-7.4(a), as well as all waivers granted to health care professionals and the reasons therefor and all emergency uses by health care professionals of sharp devices which do not contain integrated safety features.

(c) All facilities shall include in their quarterly reports, a list of all procedures for which there is no available sharp device with integrated safety features or needleless device.

(d) All quarterly reports shall be sent to the following address:

Director

Research and Development

Division of Health Care Systems Analysis

New Jersey Department of Health and Senior Services

225 East State Street, 8th Floor

Trenton, New Jersey 08625